

1

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## STERILE PACKAGE AND METHOD OF MAKING SAME

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5 Claims. (Cl. 206—63.2)

This invention relates to a sterile package, with particular reference to the packaging of medical and surgical articles or implements.

It is an object of the invention to provide a package composed wholly or partially of transparent plastic sheet material, which package is securely sealed so that it can be opened readily only at a predetermined point or points and in such a manner that its contents can be removed from the package without touching any non-sterile surface or can be used directly from the package without handling, thus avoiding contamination.

A further object is to provide such a package which is capable of being sterilized by gas after being sealed, and which is composed largely of a gas-impermeable material for protection of the contents, at least the inner surfaces of the package being of a material which is non-reactive with the latex or vinyl plastic compounds of which the packaged items may be made.

Another object is to provide a package which has a relatively long shelf life—e.g., two years or more.

A further object is to provide certain improvements in the form, construction, arrangement and material of the package, by which the above named and other objects may effectively be attained.

A practical embodiment of the invention is shown in the accompanying drawings, in which:

Fig. 1 represents a perspective view of a piece of laminated plastic sheeting, on an enlarged scale and parts being broken away;

Fig. 2 represents a perspective view of a complete package containing, for instance, a catheter, parts being broken away to show approximately a transverse section;

Fig. 3 represents a detail view on an enlarged scale, partly in perspective and partly in section on the line III—III of Fig. 2, parts being broken away;

Fig. 4 represents a detail elevation of a segment of a catheter showing how it is releasably secured to a supporting card;

Fig. 5 represents a detail elevation of the engaging parts of a pair of sealing rollers;

Fig. 6 represents, diagrammatically, an assembly of apparatus for effecting sterilization of the packages;

Figs. 7, 8 and 9 represent detail perspective views illustrating the manner of opening the package and making its contents available for use.

Referring to the drawings, the package is made from laminated plastic sheeting, and preferably from sheeting comprising a layer 1 of polyethylene on which is bonded a thinner layer 2 of "Mylar" polyester film (Du Pont brand of polyethylene terephthalate resin). In actual practice it has been found that a layer 1 having a thickness of about 2 to 3 mils, bonded to a layer 2 having a thickness of about 1/2 to 1 mil, constitutes a satisfactory sheet for the intended purpose. To form the package, two such sheets are assembled with their polyethylene faces toward each other and with the desired contents (e.g., a catheter A and supporting card B) between them. The side edges of the package are heat-sealed together

2

by passing them between a heated ridged steel sealing wheel C and smooth surfaced roller D (Fig. 5), which may desirably be of silicone rubber, so dimensioned as to seal the facing polyethylene layers together along spaced parallel lines 3 (Fig. 3), while the ends of the package are sealed by means of a heated ridged sealing bar designed to seal the faces together along spaced parallel lines 4 having substantially the same appearance and effect as the seal-lines 3 and extending across them at each corner of the package, as shown at 5.

The characteristics of the plastic materials constituting the layers 1 and 2, as they have special significance in the present case, are that both materials are strong, chemically inert and not subject to deterioration with time under normal conditions. The polyethylene (layer 1) is permeable to gas under pressure and is thermoplastic. The "Mylar" (layer 2) is impervious to gas and has thermal stability at temperatures where the polyethylene layers can be sealed together. In addition to the gas-permeability of the polyethylene, it is desirable to provide a "gas window" in the form of a strip 4' of microporous material (narrow dental tape having proven satisfactory) sealed between the two films and extending from the interior of the package to an edge or end thereof, as shown in Fig. 2.

When a package has been made as described above it contains not only such articles as the catheter A and card B, but also a certain amount of air, since packaging in the absence of air is difficult and awkward. To effect sterilization, the package is placed in a vacuum chamber, indicated at 6 (Fig. 6) and is subjected to a full vacuum (27 in.) for about 5 minutes. During this period the air in the package is substantially exhausted as some of it permeates outwardly through the sealed lines 3 and 4, which are narrow walls of polyethylene having a thickness slightly less than the sum of the polyethylene layers, while most of it flows quite rapidly out through the microporous strip 4'. Following this air exhaustion step the package is subjected (normally in the same chamber) to an atmosphere of sterilizing gas under pressure, a suitable gas being "Carboxide" (10% ethylene oxide and 90% CO<sub>2</sub>) at a pressure of one or more atmospheres. A sufficient amount of the gas permeates into the more or less collapsed package, mostly through the strip 4', as well as through the polyethylene walls of the seal-lines, to serve the purpose of sterilization of the contents. The duration of the pressure treatment depends somewhat on the pressure used and on the temperature of the gas, which passes through the polyethylene more rapidly with an increase in temperature.

It is important to attain full vacuum as quickly as possible in order to prevent the spores of any bacteria which may be present from drying out; it has been found that the ethylene oxide cannot readily penetrate and kill a dry spore, while it is highly effective in the treatment of those which are not too dry. Since the strip 4' is microporous, it effectively filters out air-borne bacteria and the like.

While the foregoing description refers generally to "a package," it will be understood that the packages and their contents are normally assembled in a continuous production line, and that many such packages are subjected simultaneously to the sterilization operation. In the course of continuous assembly in the lengthwise direction of the package the strips 4' (twice as long as shown) may conveniently be inserted across alternate areas where the packages are to be cut apart after end sealing; thus, after cutting, one such strip will form a "gas window" at the rear end of one package while the other strip forms the "window" in the front end of the next package.

As an additional feature of great practical importance, a package of the nature shown herein is provided with